K033295

OCT 2 8 2003



## SECTION E
## 510(k) SUMMARY

### 1. SUBMITTER INFORMATION:


| | |
|---|---|
| Name: | NovaMin Technology, Inc. |
| Address: | 13709 Progress Blvd., #23<br>Alachua, Florida 32615 USA |
| Phone: | (386) 418-1551 |
| Facsimile: | (386) 418-1465 |
| Contact: | David C. Greenspan, Ph.D. |


| | |
|---|---|
| Preparation Date: | September 2, 2003 |

### 2. DEVICE NOMENCLATURE:

| | |
|---|---|
| Trade Name: | Butler Nucare® Root Conditioner with NovaMin® |
| Common Name: | Inorganic apatite-forming tooth root conditioner and dentin tubule occluder |
| Classification Name: | Cavity Varnish |

### 3. LEGALLY MARKETED PREDICATE DEVICE:

| | |
|---|---|
| Device Name: | Quell™ Desensitizer |
| 510(k) Number: | K010957 |
| Applicant: | Jeneric/Pentron, Inc. |

### 4. DEVICE DESCRIPTION:

Butler Nucare® Root Conditioner with NovaMin® is a biologically-compatible device designed to condition exposed tooth roots and to physically occlude dentin tubules for the management of sensitive teeth. Butler Nucare® Root Conditioner with NovaMin® is an aqueous suspension of an inorganic particulate, NovaMin® (calcium sodium phosphosilicate), composed of elements that occur naturally in the body's hard tissues (Ca, Na, Si, P, and O). When exposed to an aqueous environment, NovaMin® undergoes a rapid surface reaction, allowing it to physically adhere to exposed root dentin and to physically occlude tubules. Within a short period of time, essentially all of the NovaMin® reacts to form hydroxycarbonate apatite (HCA), which is chemically and structurally similar to natural tooth mineral.

### 5. INTENDED USE:

Butler Nucare® Root Conditioner with NovaMin® is a two-phase product intended for the rapid relief of hypersensitivity associated with exposed tooth root dentin. Studies have shown that Butler Nucare® Root Conditioner with NovaMin® is effective at occluding exposed dentinal tubules, which has been shown in the literature to be associated with a reduction in hypersensitivity.

## 6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of Butler Nucare® Root Conditioner with NovaMin® and Quell™ Desensitizer are similar, but not identical. Both devices are designed to relieve hypersensitivity associated with exposed dentin by the deposition of a calcium phosphate layer onto the tooth surface. Both devices are supplied in two phases that are rich in calcium and phosphate ions, which combine to produce a calcium phosphate layer that occludes dentinal tubules and blocks hydrodynamic flow. The primary difference between the two devices is that Butler Nucare® Root Conditioner with NovaMin® supplies the calcium and phosphate ions in an aqueous suspension of bioactive glass, whereas Quell™ Desensitizer supplies the ions in an aqueous solution of calcium chloride and potassium phosphate.

## 7. SAFETY AND PERFORMANCE DATA:

The biocompatibility of Butler Nucare® Root Conditioner with NovaMin® was evaluated for cytotoxicity (L-929), intracutaneous irritation, maximization sensitization, and acute systemic toxicity. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of Butler Nucare® Root Conditioner with NovaMin® was evaluated using an *in vitro* dentin block model. The results indicate that Butler Nucare® Root Conditioner with NovaMin® occludes a statistically significant number of tubules when compared with both positive and negative controls.

## 8. CONCLUSIONS:

Butler Nucare® Root Conditioner with NovaMin® is considered to be substantially equivalent to the legally marketed predicate device, Quell™ Desensitizer (K010957). The provided *in vitro* performance and biocompatibility data demonstrate the safety and efficacy of Butler Nucare® Root Conditioner with NovaMin® for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2003

Mr. David C. Greenspan
Responsible Third Party Official
NovaMin Technology, Incorporated
13709 Progress Boulevard #23
Alachua, Florida 32615

Re: K033295
Trade/Device Name: Butler Nucare® Root Conditioner with NovaMin®
Regulation Number: 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: October 13, 2003
Received: October 14, 2003

Dear Mr. Greenspan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

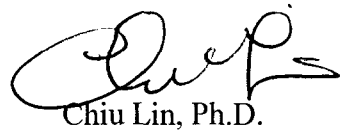
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# SECTION D
# STATEMENT OF INDICATIONS FOR USE

**510(k) Number (if known):** _____

**Device Name:** Butler Nucare® Root Conditioner with NovaMin®

**INDICATIONS FOR USE:**

Butler Nucare® Root Conditioner with NovaMin® is a two-phase product intended for the rapid relief of hypersensitivity associated with exposed tooth root dentin. Studies have shown that Butler Nucare® Root Conditioner with NovaMin® is effective at occluding exposed dentinal tubules, which has been shown in the literature to be associated with a reduction in hypersensitivity.

Kevin Mulley for ASR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033295

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR (Per 21 CFR 801.109) Over-The-Counter Use _____